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CHAPTER 7: INDUSTRY SNAPSHOT AND COMPETITION LAW: PHARMACEUTICALS

I. OVERVIEW

The Hearings examined the impact of competition law and policy on cost, innovation, and access to drug products in the pharmaceutical industry. After reviewing the importance of patent protection and competition in spurring pharmaceutical innovation, the Hearings focused on the role of pharmacy benefit managers (PBMs) and the effects of direct-to-consumer (DTC) advertising on consumer demand for, and pricing of, pharmaceutical products.

Representatives from the pharmaceutical industry and legal, economic, and academic experts spoke at the Hearings on pharmaceutical topic panels, including: Generics and Branded Pharmaceuticals (September 10, 2002); Advertising and Pharmaceuticals: DTC Advertising and Promotion (September 10, 2002); and Pharmaceuticals: Formulary Issues (June 26).[1] This chapter provides a brief overview of the drivers of competition for pharmaceutical products, discusses Commission initiatives in the pharmaceutical industry and highlights the contentious public issues surrounding PBMs and DTC advertising.

To date, most empirical evidence suggests that PBMs have lowered costs for health plan sponsors. Nonetheless, the use of PBMs as intermediaries between pharmaceutical manufacturers and health plan sponsors has raised public concern about whether PBMs increase pharmacy benefit costs for health plan sponsors and their enrollees. Pursuant to a legislative directive, the Commission is examining one particular aspect of these allegations – whether it costs more for a health plan sponsor to use mail order pharmacy services integrated with a PBM than to use non-integrated mail order or retail pharmacies.

Similarly, the effects of DTC advertising have been subject to debate. Currently available empirical evidence does not support the allegations that DTC advertising increases inappropriate prescription of, or prices for, pharmaceutical products. Indeed, research shows that truthful and non-misleading advertising generally benefits consumers by providing them with useful information about their health care and treatment options.[2] Nevertheless, definitive conclusions await the development of better empirical evidence about the effects of DTC advertising of prescription drugs.

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[1] A complete list of participants on these and other panels is available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcare hearings/completeagenda.pdf. These issues were also considered at a workshop held by the Commission on September 10, 2002. A complete list of participants in the workshop is available *infra* Appendix A and *at* http://www.ftc.gov/ogc/healthcare/.

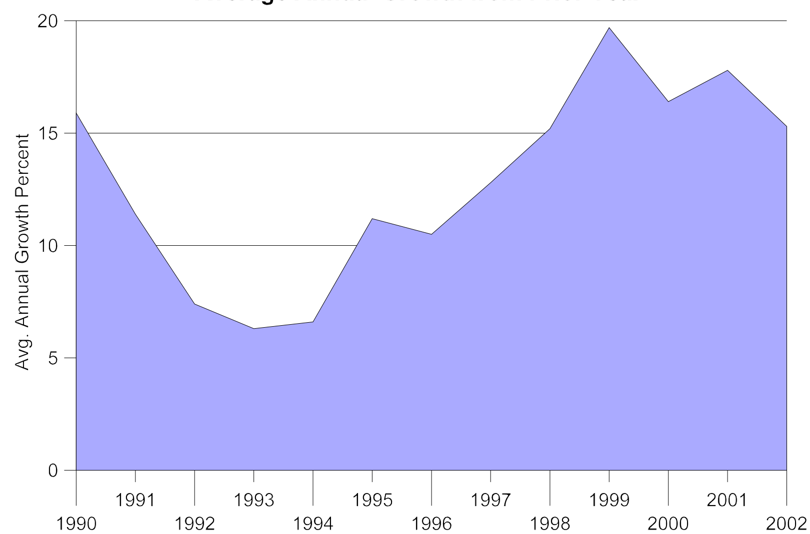
[2] *See, e.g.*, PAULINE M. IPPOLITO & JANIS K. PAPPALARDO, FEDERAL TRADE COMM'N, ADVERTISING NUTRITION & HEALTH: EVIDENCE FROM FOOD ADVERTISING 1977-1997 (2002), *available at* http://www.ftc.gov/opa/2002/10 /advertisingfinal.pdf; PAULINE M. IPPOLITO & ALAN D. MATHIOS, FEDERAL TRADE COMM'N, INFORMATION AND ADVERTISING POLICY: A STUDY OF FAT AND CHOLESTEROL CONSUMPTION IN THE UNITED STATES, 1977-1990 (1996).

II. BACKGROUND ON INNOVATION IN THE PHARMACEUTICAL INDUSTRY

The role of prescription pharmaceutical drugs has changed significantly over the last 25 years. Medicines now exist to treat conditions that previously had no treatment or required lengthy hospital stays and/or surgery, allowing health care providers to employ less invasive treatments.[3] Advances in science and technology have given researchers more sophisticated knowledge of the root causes of diseases. Scientists can more effectively design medicines to attack specific diseases, resulting in the invention of new medicines.[4]

U.S. spending on pharmaceutical products mirrors this changing role. U.S. spending on pharmaceuticals increased to $140.6 billion in 2001, more than triple the amount in 1990.[5] Total U.S. spending for drug products accounts for approximately 11 percent of personal health care spending.[6] Figure 1 shows the annual rate of increase in spending on prescription pharmaceuticals during the last decade.[7] One report estimates that approximately half of the increase in spending is due to increased utilization, and that the remainder of the increase is split evenly between increases in retail prices and increases in the use of more expensive drugs.[8]

Figure 1: National Prescription Health Expenditures Average Annual Growth from Prior Year



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[3] PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA (PHRMA), INSIGHTS 2003: HIGHLIGHTS FROM THE PHARMACEUTICAL INDUSTRY PROFILE 3 (2003), *available at* http://www.phrma.org/publications/publications//2003-10-07.892.pdf.

[4] *Id.*

[5] Kaiser Family Found., *Prescription Drug Trends* 1 (May 2003), *at* http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14267.

[6] *Id.*

[7] Centers for Medicare & Medicaid Services, *Health Accounts: National Health Expenditures 1965-2013, History and Projections by Type of Service and Source of Funds: Calendar Years 1965-2013*, *at* http://www.cms.hhs.gov /statistics/nhe/default.asp#download (last modified Mar. 24, 2004).

[8] Kaiser Family Found, supra note 5, at 2. *See also* Bhattacharjya 9/10/02 at 173.

This increase in spending for pharmaceutical products has been coupled with an increase in research and development (R&D) spending to develop and bring to market new pharmaceutical products. From 1990 to 2001, annual R&D spending in the pharmaceutical industry increased from $8 billion to $30 billion.[9]

The Commission examined extensively the drivers behind this increased R&D spending and pharmaceutical innovation in its October 2003 Report, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (FTC Patent Report)*.[10] The *FTC Patent Report* found both patents and competition play an essential role in spurring innovation in the pharmaceutical industry. Patents spur innovation in several different ways. First, patents create incentives for brand-name companies to innovate by excluding others from making, using, or selling a claimed invention for a specific period of time.

Second, patents disclose to the public information that might otherwise remain a trade secret. Such disclosure encourages innovation by giving generic companies an opportunity to design around brand-name patents.[11] Panelists at the Health Care Hearings supported the *FTC Patent Report's* conclusion that patent protection is essential to innovation in the pharmaceutical industry.[12] Innovation in this industry is costly and unpredictable as it requires significant amounts of pioneering research to discover and test new drug products. Patent protection allows pharmaceutical firms to recoup the substantial capital investments made to discover, test, and obtain regulatory approval of these new drug products. Box 7-1 references some of the empirical studies of the role of patents in spurring innovation in the pharmaceutical industry.

A. Types of Innovation in the Pharmaceutical Industry

The *FTC Patent Report* describes two main types of innovation: (i) discrete innovation;

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[9] PHRMA, *supra* note 3, at 6 (these expenditures are not adjusted for inflation).

[10] *See* FEDERAL TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) [hereinafter FTC PATENT REPORT], *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf. The report also described the regulatory process used by the Food and Drug Administration to ensure pharmaceutical products are safe and effective. *Id.* § 3, at 6-9.

[11] *Id*. § 3, at 9 ("Panelists reported that patent protection promotes innovation in the pharmaceutical industry by creating incentives for brand-name companies to innovate, and by disclosing inventions, thereby encouraging generic companies to innovate by designing around brand-name company patents.").

[12] Bhattacharjya 9/10/02 at 177; Glover 9/10/02 at 182-83; Schultz 9/10/02 at 211; Lock 9/10/02 at 220-21; McCluskey 9/10/02 at 221.

Box 7-1 ***Empirical Studies on the Role of Patents in Spurring Innovation in the Pharmaceutical Industry***

Empirical studies have shown that patents play an essential role in spurring innovation in the pharmaceutical industry. One study conducted by Edwin Mansfield analyzed a random sample of 100 firms, excluding very small firms, from twelve broadly defined industries. The study found patents to be essential for the pharmaceutical and chemical industries in developing or introducing thirty percent or more of their inventions. *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCIENCE 173, 174-75 (1986); *see also* FTC, PATENT REPORT § 2, at 11 (citing Mansfield study). The pharmaceutical industry participants reported that "60% of inventions would not have been developed and 65% would not have been commercially introduced absent patent protection." FTC, PATENT REPORT § 2, at 11 (citing Mansfield study); Mansfield, *supra*, at 175.

Another study by Richard C. Levin, Alvin K Klevorick, Richard R. Nelson and Sidney G. Winter analyzed survey responses from 650 R&D managers representing 130 lines of business. This study found patents were especially important in the pharmaceutical drug industry to prevent duplication. *See* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, *in* BROOKINGS PAPERS ON ECONOMIC ACTIVITY 795-96 (1987); *see also* FTC, PATENT REPORT § 2, at 11 (citing Levin, Klevorick, Nelson and Winter study).

A more recent study by Wesley M. Cohen, Richard R. Nelson and John P. Walsh found that in the pharmaceutical industry patents were effective appropriability mechanisms for more than 50% of all product innovations. WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) 32 tbl.1 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), *at* http://papers.nber.org/papers/w7552.pdf; *see also* FTC, PATENT REPORT § 2, at 11-12 (citing Cohen, Nelson and Walsh study).

and (ii) incremental innovation.[13] Innovation can occur at many points along the continuum, from discrete to incremental, but these categories help classify innovation in the pharmaceutical industry.

1. Discrete Innovation

Discrete innovation focuses on the "discovery and development of new chemical or molecular entities to make small molecule drug products."[14] The benefits of investing large amounts of time and money into such discoveries can be very high. For example, "[t]he discovery of a chemical molecule that is both efficacious and safe for human usage can result in

[13] Although these are the two main categories, innovation may occur somewhere between these two types. FTC PATENT REPORT, *supra* note 10, at 4.

[14] *Id.* at 4-5.

a totally new drug product."[15] The benefits of discrete innovation, however, do not come without high fixed costs and risks that the effort will not produce a marketable product. Brand-name companies can spend 10-15 years on development for a new drug before the product enters the market.[16] During this time brand-name companies incur significant costs at a high risk that their product may not make it out of clinical trials.[17]

2. Incremental Innovation

Incremental innovation "consists of enhancing known chemical entities by formulating new dosage forms or additional methods of use for existing chemical entities."[18] The term "incremental" generally refers to advances in technology that are built on the features or elements of existing technology.[19] Drugs formed this way are referred to as incrementally modified drugs (IMDs).[20]

The *FTC Patent Report* describes three ways incremental innovation is achieved. One is through new formulations, which include such things as changes in dosage forms or new ways of administering approved drugs. The second method is combining two previously approved active ingredients to form a new product. The third is the use of derivatives of previously approved drugs to form a new product.[21] There are a variety of views about the benefits of these modified drugs, ranging from the view that IMDs bring significant health enhancements to consumers to the view that IMDs only serve to extend a brand-name company's "patent monopolies beyond the patent expiry of the new chemical entity … by a matter of years, not days or weeks or months."[22]

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[15] *Id.* at 5.

[16] *Id.* at 5; *see* Gregory J. Glover, *Competition in the Pharmaceutical Marketplace* 3 (3/19/02) (stating that the average cost to develop a new drug is $802 million) [hereinafter Glover (stmt)], *at* http://www.ftc.gov/opp/intellect/020319gregoryj glover.pdf.

[17] *See* Glover (stmt), *supra* note 16, at 3 ("On average, economists estimate that it takes 10-15 years to develop a new drug. Most drugs do not survive the rigorous development process – only 20 in 5,000 compounds that are screened enter preclinical testing, and only 1 drug in 5 that enters human clinical trials is approved by the FDA as being both safe and effective.").

[18] FTC PATENT REPORT, *supra* note 10, at 8.

[19] *Id.* at 8; *see also* THE NAT'L INSTITUTE FOR HEALTH CARE MGMT., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 5 (2002) [hereinafter NIHCM, INNOVATION REPORT], *available at* http:// www.nihcm.org/innovations.pdf.

[20] NIHCM, INNOVATION REPORT, *supra* note 19, at 5.

[21] *Id.* at 5, 8.

[22] FTC PATENT REPORT, *supra* note 10, at 9.

B. The Role of Competition in Spurring Pharmaceutical Innovation

Several panelists at the health care hearings highlighted the importance of competition to spur innovation. For example, some panelists suggested that the incentives to innovate provided by patent rights should be balanced against the competition provided by generic drugs.[23] The *FTC Patent Report* has articulated how competition spurs pharmaceutical innovation. First, brand-name companies with patented drugs are increasingly competing with one another, particularly within the same therapeutic class. Second, provisions in the Hatch-Waxman Amendments have fostered competition from generics by streamlining the generic drug approval process.[24]

Competition Among Brand-Name Companies. The *FTC Patent Report* indicated that brand-name pharmaceutical companies believe that competition among brand-name companies continues to increase because the period of market-exclusivity between the introduction of a breakthrough medicine and the introduction of a competing therapeutic agent has been consistently shrinking.[25] Although brand-to-brand competition may have increased in those therapeutic areas in which demand for the drugs is likely to increase, one commentator has suggested that price competition among several drug products in a therapeutic class can be limited.[26]

Competition From Generic Drug Products. The Hatch-Waxman Amendments govern the generic drug approval process and have played a major role in spurring additional competition in the pharmaceutical industry. The Amendments "established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers."[27] The Amendments also streamlined procedures for allowing generic drug applicants an

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[23] Lock 9/10/02 at 220-21; McCluskey 9/10/02 at 221.

[24] FTC PATENT REPORT, *supra* note 10, at 10-12. Another form of competition that may affect innovation is the competition among generic firms for the same brand-name product.

[25] *Id.* at 10-11. *See also* Thomas H. Lee, *'Me-Too' Products: Friend or Foe?*, 350 NEW ENG. J. MED. 211 (2004).

[26] FTC PATENT REPORT, *supra* note 10, at 10 n.46 (citing NIHCM, INNOVATION REPORT, *supra* note 19, at 3).

[27] FEDERAL TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at i (2002) [hereinafter FTC GENERIC DRUG STUDY], *available at* http://www.ftc.gov/os/ 2002/07/genericdrugstudy.pdf; *see also* FTC PATENT REPORT, *supra* note 10, at 11.

opportunity to gain FDA approval prior to patent expiration.[28] Since enactment of Hatch-Waxman in 1984, barriers to competition have been lowered, and price competition in those markets with generic entry has increased significantly.[29]

Competition from generic drugs can deliver large price savings to consumers, because generic drugs are typically far less expensive than their corresponding brand-name versions. A Congressional Budget Office (CBO) study attempted to quantify the magnitude of this effect by analyzing retail pharmacy data from 1993 and 1994. The study found that the average price of a generic prescription was approximately half of the average price of a brand-name prescription.[30] The CBO estimated that the availability of generic drugs saved purchasers between $8 billion and $10 billion in 1994 alone.[31]

Other empirical economics literature also finds procompetitive effects associated with the introduction of generic drugs.[32] This literature points to significant short-run competitive impacts of generic entry that can lead to substantial benefits for consumers of prescription drugs.[33]

The *FTC Patent Report* highlights two provisions of Hatch-Waxman that have played a significant role in spurring increases in generic competition: the 180-day exclusivity provision and the 30-month stay provision. Under the 180-day provision, the first generic firm to file an application for a new drug is granted 180 days of marketing exclusivity if the generic firm

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[28] FTC PATENT REPORT, *supra* note 10, at 11. Brand-name companies must provide the FDA with information regarding patents that cover their drug products, which the FDA then lists in a publication commonly known as the "Orange Book." For an overview of Orange Book procedures, *see* DuPont 9/10/02 at 162-68. *See also* 21 U.S.C. § 355(j)(7)(A); FTC GENERIC DRUG STUDY, *supra* note 27, at 25-37 (Chapter 3: "Settlements Related to Paragraph IV Certifications"). Generic drug companies that seek FDA approval prior to patent expiration must give notice to brand-name companies stating that the listed patents are invalid or not infringed by the generic product.

[29] FTC PATENT REPORT, *supra* note 10, § 3, at 11 n.50-51.

[30] CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 28 (1998), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0.

[31] *Id*. at 31. *See also* McCloskey 9/10/02 at 197-98 (discussing how seniors benefit from generic drug usage).

[32] *See, e.g.*, DAVID REIFFEN & MICHAEL R. WARD, GENERIC DRUG INDUSTRY DYNAMICS (Bureau of Econ. of the Federal Trade Commission, Working Paper No. 248, 2002), *available at* http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf; *see also* Reiffen 9/10/02 at 204-10; Henry Grabowski & John M. Vernon, *Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331 (1992).

[33] FTC PATENT REPORT, *supra* note 10, at 11 n.52 (an additional benefit is that generic competition has forced brand-name companies to develop new products to replenish their revenue stream).

certifies that its product does not infringe any of the brand-name company's patents on the drug product or if the generic firm challenges the validity of the brand-name company's patent. During this 180-day exclusivity period the FDA may not approve subsequent generic applications for the same drug.[34] The 180-day exclusivity provision has provided increased incentives for a generic firm to be the first to file an application to market its product. As the first to file, a generic has the potential to "reap the reward" of being the only generic product in the market for a set period of time.[35] The provision also provides more incentives for companies to challenge patents and develop alternatives to patented drugs.[36]

A brand-name company may receive a 30-month stay of FDA approval of a generic applicant if the brand-name company has received notice of the filing of such a generic application and files suit for patent infringement within 45 days of that notice. [37] According to the legislative history, the stay allows for the commencement of a lawsuit and takes into account the patent owner's rights while still encouraging generic entry.[38]

C. Policy Choices That Could Undermine Innovation and Competition in the Pharmaceutical Industry

Both patent protection and competition have led to substantial investment and innovation in the pharmaceutical industry. Certain policy choices currently being debated, however, have the potential to undercut certain aspects of patent protection and competition. These new policy choices warrant serious discussion and debate.

One policy choice involves price regulation or price controls to lower prescription drug prices. Levels of prescription drug spending have increased in recent years due to increases in both the number of prescriptions and prices. Many consumers face hardships in keeping up with these escalating prices.[39] Thus, the impetus to consider price regulation or price controls is understandable.

Before any move in this direction, however, it is important to review the history of attempts to solve public problems through price controls. Price controls have typically led to

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[34] FTC GENERIC DRUG STUDY, *supra* note 27, at vi.

[35] FTC PATENT REPORT, *supra* note 10, at 12.

[36] *Id.* at 12; *see also* Granutec, Inc. v. Shalala, 139 F.3d 889, 891 (4th Cir. 1998).

[37] FTC PATENT REPORT, *supra* note 10, at 12; FTC GENERIC DRUG STUDY, *supra* note 27, at ii; H.R. REP. NO. 98-857, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

[38] FTC PATENT REPORT, *supra* note 10, at 12.

[39] Lock 9/10/02 at 191-92 (describing how many seniors cannot afford their prescription drugs and how they sacrifice their financial savings to pay for necessary medication).

significant market place distortions that harmed consumers.[40] Price controls are also difficult to administer.[41] Price controls that reduce prices too low reduce output and capacity, lower the quality of the services that are provided, and diminish the incentives for innovation, including ongoing R&D.[42] Thus, price controls on pharmaceuticals have a significant potential to harm consumers.[43]

Another policy choice surrounds whether government should use its purchasing power to purchase drugs on behalf of consumers and thereby lower prices. One risk of this approach is the potential for the government to become a "monopsonist." As Chapter 6 reflects, monopsony is "market power exercised by buyers rather than sellers" that lets the buyer "reduce the purchase price by scaling back its purchases."[44] The *1992 Horizontal Merger Guidelines* (*Merger Guidelines*) provide that market power encompasses the ability of a single buyer "to depress the price paid for a product to a level that is below the competitive price and thereby depress output. The exercise of market power by buyers ('monopsony power') has adverse effects comparable to those associated with the exercise of market power by sellers."[45] A likely market effect of government-based monopsony power would be not only lower prices for pharmaceutical products, but also reduced investment in R&D. Subsequently, less innovation in the pharmaceutical industry might result over the longer term. Once again, such a marketplace distortion could lead to significant consumer harm.

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[40] *See, e.g.*, Stuart M. Butler, *The Fatal Attraction of Price Controls*, *in* HEALTH POLICY REFORM: COMPETITION AND CONTROLS (Robert B. Helms, ed. 1993). *See also* W. Duncan Reekie, *How Competition Lowers the Costs of Medicines*, 14 PHARMOECONOMICS 107, 112 (1998); PATRICIA M. DANZON ET AL., THE IMPACT OF PRICE REGULATION ON THE LAUNCH DELAY OF NEW DRUGS – EVIDENCE FROM TWENTY-FIVE MAJOR MARKETS IN THE 1990S (Nat'l Bureau of Econ. Research, Working Paper No. 9874, 2003).

[41] Butler, *supra* note 40.

[42] A study by the U.S. Department of Health and Human Services warns that "[g]overnment controls on drug access and pricing may result in decreased revenues, which reduce monies available for research and development" and thus lead to slowed or delayed development and introduction of new drugs into the marketplace. OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING & EVALUATION, U.S. DEP'T. OF HEALTH & HUMAN SERVICES, SECURING THE BENEFITS OF MEDICAL INNOVATION FOR SENIORS: THE ROLE OF PRESCRIPTION DRUGS AND DRUG COVERAGE 11 (2002).

[43] John E. Calfee, *Pharmaceutical Price Controls and Patient Welfare*, 134 ANN. INTERN. MED. 1060 (2001).

[44] IIA PHILLIP E. AREEDA ET AL., ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 575, at 363 (2d ed. 2002).

[45] U.S. DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 0.1 (1992), *available at* http://www.ftc.gov/bc/docs/horiz mer.htm.

III. COMMISSION INITIATIVES TO ENSURE CONSUMERS RECEIVE THE BENEFITS OF PHARMACEUTICAL COMPETITION

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers to ensure that consumers receive the benefits of generic drug competition. One type of conduct involves allegedly anticompetitive agreements between brand-name and generic companies.[46]

In a recent opinion, the Commission ruled that Schering-Plough Corporation (Schering), Upsher-Smith Laboratories, Inc. (Upsher), and American Home Products (AHP) entered into illegal agreements in 1997 and 1998 to delay the entry of lower-cost generic competition for Schering's prescription drug K-Dur 20.[47] Schering and its potential generic competitors, Upsher and AHP, settled patent litigation on terms that included substantial payments by Schering to those potential rivals in return for agreement to defer introduction of the generic products. The Commission held that these provisions were unfair methods of competition and entered an order that would bar similar conduct in the future.[48]

The Commission also has taken antitrust enforcement action against other types of improper conduct. These actions charged abuse of FDA regulations governing patent listings[49] and potentially anticompetitive agreements between rival generic manufacturers.[50] For example, the Commission alleged a decade-long pattern of anticompetitive acts by Bristol-Myers Squibb (BMS) to obstruct the entry of low-price generic competition for three of its widely-used pharmaceutical products: two anti-cancer drugs, Taxol and Platinol, and the anti-anxiety agent BuSpar. BMS allegedly abused FDA regulations to block generic entry, misled the U.S. Patent and Trademark Office to obtain unwarranted patent protection, and filed baseless patent infringement lawsuits to deter entry by generics.

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[46] *See, e.g.*, *In re* Bristol-Myers Squibb Co., No. C-4076 (Apr. 14, 2003) (decision and order), *available at* http://www.ftc.gov/os/2003/04/bristol
myerssquibb do.pdf; *In re* Abbott Laboratories, No. C-3945 (May 22, 2000) (decision and order), *available at* http://www.ftc.gov/os/2000/05/ c3945.do.htm; *In re* Geneva Pharmaceuticals, Inc., No. C-3946 (May 22, 2000) (decision and order), *available at* http://www.ftc.gov/os/2000/05/ c3946.do.htm; *In re* Hoechst Marion Roussel, Inc., No. 9293 (May 8, 2001) (decision and order), *available at* http://www.ftc.gov/os/2001/05/ hoechstdo.htm; FTC v. Mylan Laboratories, Inc., 62 F. Supp. 2d 25 (D.D.C. 1999), *available at* http://www.ftc.gov/os/1999/07/mylan.pdf.

[47] *In re* Schering-Plough Corp. et al., No. 9297 (Dec. 8, 2003) (final order), *available at* http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf, *appeal docketed*, No. 04-10688-AA (11th Cir. filed Feb. 13, 2004). K-Dur is used to treat people with low potassium.

[48] *Id.*

[49] *See, e.g.*, *Bristol-Myers*, No. C-4076 (decision and order); *In re* Biovail Corp., No. C-4060 (Oct. 2, 2002) (decision and order), *available at* http://www.ftc.gov/os/2002/10/biovaildo.pdf.

[50] *In re* Biovail Corp. & Elan Corp. PLC, No. C-4057 (Aug. 15, 2002) (decision and order), *available at* http://www.ftc.gov/os/2002/08/bioval do.pdf.

According to the FTC's complaint, BMS' illegal conduct protected nearly $2 billion in annual sales at a high cost to cancer patients and other consumers, who – being denied access to lower-cost alternatives – were forced to overpay by hundreds of millions of dollars for important and often life-saving medications.[51]

In addition, the Commission issued its comprehensive study of this industry, *Generic Drug Entry Prior to Patent Expiration*, in 2002.[52] That study examined whether the conduct that the FTC had challenged represented isolated instances or was more typical of pharmaceutical industry business practices and whether certain provisions of the Hatch-Waxman Act, which govern generic drug entry, were susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products.[53] This study found that if left unchecked, certain provisions of the Hatch-Waxman Act had the potential to be abused, thereby preventing generic drugs from becoming timely available.[54]

To combat this potential for abuse and resultant delays in generic drug competition, the Commission recommended two major changes to the Hatch-Waxman Act. These recommendations were to provide only one 30-month stay per brand-name drug product and to require notification to the Commission of certain types of pharmaceutical company agreements.[55] The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) includes these two significant recommendations.[56] The Commission will continue to protect consumers from anticompetitive practices that inflate drug prices.

IV. PBMS: OVERVIEW AND POLICY QUESTIONS

The growth of pharmacy benefit managers (PBMs) is an important development in providing consumer access to prescription drugs. This section describes PBMs' role in administering pharmacy benefit services on behalf of their clients (*i.e.*, health plan sponsors such

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[51] The Commission cooperated in its investigation of BMS with various state attorneys general that had filed their own antitrust suits in federal court. By agreement, the States deferred to the Commission whereby the FTC assumed the lead in negotiating the conduct limitation provisions contained in the proposed order. The states entered essentially the same injunctive terms in their orders. In addition to the injunctive relief, the states will recover substantial monetary relief. *See* News Release, Federal Trade Comm'n, FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition (Mar. 7, 2003), *at* http://www.ftc.gov/ opa/2003/03/bms.htm.

[52] FTC GENERIC DRUG STUDY, *supra* note 27.

[53] *Id.*

[54] *Id*. at ii.

[55] *See Id*. at ii-vi.

[56] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, 117 Stat. 2066 (2003).

as large employers or health insurance carriers), provides overview information about the industry, and highlights the important public policy issues that panelists discussed. Public scrutiny has increased recently over PBMs' role in administering pharmacy benefit services. To date, the empirical evidence suggests that consumers with prescription drug insurance administered by a PBM save substantially on their drug costs as compared to cash-paying customers.[57] At the behest of Congress, the Commission is examining one aspect of the PBM industry – whether PBMs' mail order pharmacies save money for health plan sponsors and consumers as compared to retail pharmacies and mail order pharmacies not owned by PBMs. Congress has required the Commission to complete this study by June 2005.

A. What is a PBM?

PBMs manage the pharmacy benefit of group health plan sponsors, such as HMO plans, self-insured employers, indemnity plans, labor union plans, and plans covering public employees.[58] When an enrollee in one of these plans purchases a drug at a retail pharmacy, he or she presents a health plan card identifying the source of insurance coverage. The pharmacy will transmit the insurance coverage information to the PBM, which verifies coverage and determines if the plan covers the prescribed drug, what the plan owes as direct payment to the pharmacy, and what the enrollee's co-payment will be (if any). The PBM transmits this information back to the pharmacy, logs the payment information on its system, and transmits the billing information to health insurers. These insurers then remit payment to the PBM, which forwards payment to the retailer. This process, known as claims adjudication, is handled electronically. Ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.[59]

In the words of one panelist, PBMs are the "middlemen" between pharmaceutical manufacturers and health plans or employers.[60] PBMs contract with pharmaceutical manufacturers on behalf of the plan sponsors to obtain brand-name and generic drugs. One panelist noted that a large customer base enables the largest PBMs with the most covered lives to drive the market share of any one pharmaceutical drug product and, therefore, obtain the lowest prices from pharmaceutical manufacturers.[61] PBMs use mail order pharmacies or contract with retail pharmacies to establish networks of nearby pharmacies through which enrollees can have

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[57] *See, e.g.*, GENERAL ACCOUNTING OFFICE (GAO), EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES (2003), *available at* http://www.gao. gov/cgi-bin/getrpt?GAO-03-196. One weakness of the GAO study, however, is the lack of a baseline for comparing cost savings among customers with prescription drug insurance coverage.

[58] Richardson 6/26 at 7.

[59] *Id.* at 8.

[60] Calfee 6/26 at 46.

[61] *See* Boudreau 6/26 at 57.

their prescriptions filled. Most PBMs contract with 90 percent of the retail pharmacies in the region they serve.[62] National PBMs have established networks that include nearly all retail chain pharmacies. In these contracts, the parties agree to the dispensing fees that the PBM will pay the retail pharmacy.

B. The PBM Formulary

The main tool that PBMs use to manage pharmacy benefits is the formulary, which is a list of PBM-approved drugs for treating various diseases and conditions.[63] Through a formulary, the PBM controls the price that health plans and enrollees pay and may influence the use of various drugs and the mix of drugs dispensed.[64] Panelists reported that although PBMs design formularies, plan sponsors often demand a customized formulary that addresses various needs of their enrollees (*e.g.*, cost containment, access to certain medicines, high generic substitution, etc.).[65]

One panelist described generally how a formulary decision is made in a single therapy class for its preferred national formulary.[66] The panelist stated that an independent pharmacy and therapeutics (P&T) committee first evaluates the drugs in the particular class for clinical effectiveness and safety. Each drug is then classified for formulary purposes as "include on the formulary," "exclude from the formulary," or "optional." The next step for drugs classified as "optional" is that the P&T committee ranks them on clinical effectiveness, and then again by cost. The "optional" drugs also are examined for their market share and likely customer reaction if the PBM were to prefer certain drugs over others. After the rankings are complete, the PBM decides which drugs to include on its national formulary. As noted above, group health plans may negotiate certain aspects of a PBM's preferred national formulary.

In deciding which drugs to include in the formulary (and their placement within various tiers on the formulary), two practices come into play: (i) generic substitution; and (ii) therapeutic interchange. Generic substitution is the dispensing of a bio-equivalent generic drug product that contains the same active ingredient(s) as the brand-name drug and is, among other things, chemically identical in strength, concentration, dosage form, and route of administration as the substituted brand-name product. Generic substitution generally occurs when a consumer

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[62] Richardson 6/26 at 9.

[63] Barrueta 6/26 at 87.

[64] Richardson 6/26 at 16; *see also* Academy of Managed Care Pharmacy (AMCP), *Comments Regarding the June 26, 2003 Joint FTC-DOJ Hearings on Health Care and Competition Law and Policy (Pharmaceuticals: Formulary) (Aug.5, 2003)* 2 (Public Comment) ("[A] well-desired, properly administered formulary will assist in the effective management of a patient's overall health care.").

[65] Boudreau 6/26 at 65.

[66] *Id.* at 60-64. *See also* Barreuta 6/26 at 92.

presents a prescription for a brand-name drug and the pharmacist fills the prescription with a generic version of the drug product without the need for prior physician authorization. Because generic drugs are substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs.[67]

Therapeutic interchange involves a pharmacist substituting a therapeutically equivalent, but distinct, drug product for the drug product referred to on the consumer's prescription (*e.g.*, two brand-name drug products that treat the same ailment). Prior physician authorization is required before a pharmacist is allowed to interchange one brand-name drug for another.

The co-pays that enrollees must pay are determined with all of these variables in mind. Co-pays significantly influence drug utilization. Most group health plan sponsors negotiate a three-tiered co-pay arrangement with the PBM, with the lowest co-pay for generic drugs, the middle tier for brand-name drugs with no generic equivalent, and the highest co-pay for brand-name drugs with a generic equivalent.[68] Some plan sponsors negotiate a fourth tier for drugs not included on the PBM formulary, and so-called lifestyle drugs, *e.g.*, drugs to combat hair loss.[69] The ascending rates of the co-pays are designed to create an incentive for the enrollee to prefer the lowest cost, yet clinically effective, alternative.

Greater formulary compliance allows the PBMs to negotiate with the pharmaceutical manufacturer for better prices, because formulary compliance is an indication of the ability of the PBM to steer enrollees to various drugs. Thus, formulary compliance allows the PBM to negotiate what it can deliver for the manufacturers in terms of growth of their market share or avoidance of the manufacturer losing market share.[70]

Plan sponsors may negotiate with PBMs to provide enrollees incentives to use the PBM network pharmacies so that the PBM has greater control of reimbursement and adherence to formulary drugs. Those incentives range from differential co-pays to denial of coverage for out-of-network purchases. Plan sponsors and PBMs also negotiate over incentives for enrollees to use mail order distribution for maintenance medications.[71] Mail order distribution typically is handled through the PBMs' own internal mail order pharmacies or through mail order pharmacies under contract with another PBM.

C. Flow of Payments for Drug Benefits and PBM Services

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[67] *See* Dicken 6/26 at 32.

[68] Richardson 6/26 at 19.

[69] *Id.* at 19.

[70] Barreuta 6/26 at 91.

[71] Maintenance drugs are those used for treatment of chronic conditions, *e.g.*, hypertension, diabetes, etc.

To perform its services, a PBM enters contracts with healthcare plans, retail pharmacies, and drug manufacturers. When a PBM establishes retail networks, it contracts with retail pharmacies on reimbursement amounts for drugs dispensed by the pharmacy. For a given drug, the price that the PBM will reimburse a retail pharmacy is stated as a discount from a measure of wholesale price plus a dispensing fee for the pharmacy. For brand-name drugs, the "average wholesale price" (AWP) as stated by the manufacturer is used as a basis for the discount, so the price formula would be, for example, "AWP - 10% + $2.00." For generic drugs, the average price used is the "maximum allowable cost" (MAC) as specified by the PBM, so the formula might be "MAC - 10% + $2.00." Retail pharmacies are willing to offer discounts from the reference price (AWP or MAC) depending on the type of plan sponsors covered by the PBM and the exclusivity of the retail pharmacy network. The more exclusive the network, the larger the discount retail pharmacies will offer, believing that greater exclusivity is likely to bring them more customers.

The PBM's contract with a plan sponsor covers the amount that the plan sponsor will pay the retail pharmacy per prescription of each drug, as well as separate charges for the variety of PBM services that the plan sponsor may utilize. The PBM's charge to the plan sponsor per script is similar in form to the retail pharmacy contract. For brand-name drugs, it is a discount off AWP plus an administration charge per script, *e.g.*, "AWP - 5% + $0.10." For generic drugs, the charge has the same form except the discount will be from the MAC as specified by the PBM.

Finally, the contract negotiated with the pharmaceutical manufacturer may provide a rebate off the fees owed by the PBM based on (a) a percentage of AWP or some other wholesale benchmark, (b) achieving certain specified sales or market share targets, (c) preferred placement of certain drug products on the PBMs' formulary, or (d) a combination of items (a) - (c). In addition, the manufacturer may pay the PBM an administration fee and a fee for the PBM providing promotional services.

PBMs also may be paid for providing services such as drug utilization reviews, which analyze physician prescribing patterns to identify physicians who prescribe high cost drugs when lower cost alternatives are available; disease management services, which offer treatment information to, and monitoring of, patients with certain chronic diseases; or drug interaction reviews to determine what other drugs patients may be taking so that the pharmacist can ensure against adverse reactions.[72] In addition, PBMs may offer specialty pharmacy services, including the provision of certain high cost, low utilization drugs that retail pharmacies normally do not carry and that may require special means of distribution (*e.g.*, refrigeration) or professional administration.

D. Industry Overview

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[72] Richardson 6/26 at 21-22.

It is estimated that there are 60 PBMs operating in the United States today. There are three independent, full-service PBMs with national scope: Medco Health Solutions, Inc. (Medco) (formerly Merck-Medco), Express Scripts, Inc., and Caremark, Inc..[73] Some PBMs are owned by significant retail supermarket/pharmacy chains, *e.g.*, CVS's PharmaCare, Kroger's Prescription Plans, and Walgreen's Health Initiatives. Many large insurers such as Aetna and Cigna offer in-house PBM functions. In addition, there are many smaller, privately-held PBMs. The relative size and ranking of these companies varies according to the measure used, such as annual prescription expenditures, prescriptions per year, or covered lives.[74] Each measure has its own shortcomings. Overall, however, the market share figures present an industry in which three national PBMs are major players; a large share, anywhere from one-third to one-half, includes health plans and retail pharmacy chains offering PBM services; and local and regional PBMs have a significant presence.[75]

E. Competition Between PBMs: The Bidding Process

Group health plan sponsors generally procure PBM services through a bidding process. They typically issue requests for proposals to several PBMs and then evaluate the proposals based on costs and the package of services offered by each bidder. Plan sponsors, or their consultants, conduct these bid processes. Smaller employers or health plans with limited geographic scope likely will have many choices among PBMs, because smaller and more regionally oriented PBMs can meet their needs. Larger employers or health plans often turn to the largest PBMs because of their experience in serving large clients and their nationwide network of pharmacies, although several health plans and retail pharmacy chains offering PBM services also could meet their needs.

PBMs appear to compete on price and non-price dimensions. One survey of plan sponsors using PBM services showed the financial terms of the bid (such as the reimbursement rate and dispensing fee paid to pharmacies, the rebates paid to plan sponsors based on formulary drugs utilized, mail order pricing, and administrative fees) often were the key determinants in the selection of the winning bid.[76] This study also found that plan sponsors were concerned about non-price dimensions of service, such as plan design, the extent of the retail network, and mail order components. Each term or feature is balanced against each other and is driven by the

[73] The Commission announced that it had closed its antitrust investigation into Caremark Rx, Inc.'s proposed acquisition of Advance PCS on February 11, 2004 without taking any further action. *See* Statement, Federal Trade Comm'n, Caremark Rx, Inc./Advance PCS (Feb. 12, 2004), *available at* http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf.

[74] Richardson 6/26 at 11.

[75] *Id.* at 13.

[76] *See* PRICEWATERHOUSECOOPERS LLP, HEALTH CARE FINANCING ADMINISTRATION, STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT (2001), *available at* http://www.cms.gov/researchers/reports/2001/cms.pdf.

needs of the plan sponsor. For example, some want to maximize generic substitution, whereas others want to maximize rebates from manufacturers.[77]

F. Benefits of PBMs: The Evidence to Date

The General Accounting Office released a study in January 2003 that examined the effects of PBMs on the Federal Employees Health Benefits Program, enrollees, and pharmacies.[78] The report considered the prescription benefits programs offered within three health plans available to federal government employees. These three plans covered about 4.5 million lives. The largest of these plans, BCBS, held contracts with two PBMs: AdvancePCS, which handled their retail network; and Medco, which supplied their mail order pharmacy benefits. Another plan, GEHA, contracted solely with Medco. The third plan, PacifiCare, used a PBM called Prescription Solutions, which is a subsidiary of PacifiCare, which also sells independent PBM services.

Table 1: Discounts Relative to Cash Prices

	Generic Drugs	Brand-Name Drugs
Retail Pharmacy	47%	18%
PBM's Mail Order Pharmacy	53%	27%

The study compared prices that three types of customers paid for 14 brand name drugs and four generic drugs: (1) cash-paying customers, who buy at retail pharmacies; (2) health plan sponsors and their enrollees, who buy at retail pharmacies; and (3) health plan sponsors and their enrollees, who buy from a PBM's mail order facility. Table 1 shows the results of the study. The study found that the lowest average prices for 30-day supplies were obtained when the drug was purchased through the PBM's mail order pharmacy.[79] For generic drugs purchased through a retail pharmacy, enrollees in health plans paid an average 47 percent less than cash customers.

G. Issues Facing the PBM Industry

1. Transparency

Panelists discussed the significance of rebate transparency in the PBM market, including whether a PBM should be required to disclose to plan sponsors the rebates that pharmaceutical

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[77] Boudreau 6/26 at 65; *see also* Barrueta 6/26 at 105.

[78] *See* GAO, *supra* note 57.

[79] Similar relative cost saving for PBM clients have also been documented. *See* Cindy Parks Thomas et al., *Impact of Health Plan Design And Management On Retirees' Prescription Drug Use And Spending 2001*, 2002 HEALTH AFFAIRS (Web Exclusive) W408, *at* http://content.healthaffairs.org/ cgi/reprint/hlthaff.w2.408v1.

manufacturers pay PBMs for meeting certain market share targets. One panelist stated that armed with information about rebates, plan sponsors can encourage PBMs to compete more aggressively so that the plan sponsor obtains lower prices.[80] By contrast, other panelists suggested that rebate transparency can be handled through private contracts, because there is no barrier to a plan sponsor negotiating an arrangement providing it with access to the PBMs' rebate information.[81] Another panelist suggested that many plan sponsors have placed a greater emphasis on paying lower administrative fees as a trade-off for allowing PBMs to keep pharmaceutical manufacturer rebates.[82]

Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms. Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health care services, either as lower premiums for health insurance, lower out-of-pocket costs (for that portion of health care expenditures borne directly by consumers through deductibles and co-payments), or improved services. Negotiated limitations on transparency are unlikely to be so severe that health plan sponsors cannot assess the price and quality of the services they are receiving. Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract.

2. Regulation and Litigation

The American Federation of State County & Municipal Employees filed a lawsuit in 2003 alleging that the largest PBMs have engaged in unfair and deceptive practices under California state law.[83] The complaint alleges that PBMs engage in various forms of conduct designed to increase their profits, instead of benefitting employers and consumers. The case is currently pending.

In April 2004, the United States along with 20 states announced a settlement of claims

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[80] Balto 6/26 at 78. In addition to price, plan sponsors may be concerned about other PBM services such as network availability or access to a wide variety of drug products. As Section D, *supra* reflects, the current structure of the PBM industry does not suggest the potential for a PBM to exercise monopsony power over pharmaceutical manufacturers.

[81] Calfee 6/26 at 99; Balto 6/26 at 99. *See also* Hewitt Associations, LLC, *Hewitt's 2004 Future Health Care Expectations Survey: An Overview*, *at* http://was4.hewitt.com/hewitt/resource/spkrsconf/subspkrsconf/teleconferences/tapes/10-08-03.pdf (last visited June 22, 2004).

[82] Barrueta 6/26 at 105.

[83] AFSCME v. AdvancePCS, No. BC 292227, at ¶ 4 (Cal. Super. Ct., Los Angeles Cty. filed Apr. 4, 2003) (first amended representative action and complaint), *available at* http://www.hagens-berman.com/files/PBM%20Complaint%20-%20Amended%20-%20NP1049738021600.pdf.

for injunctive relief and state unfair trade practices against Medco.[84] The United States and the states alleged that Medco encouraged physicians to switch patients to different prescription drugs that earned Medco higher rebates from pharmaceutical manufacturers, but that Medco failed to pass on these savings to patients or their health plan sponsors. Both the United States and the states alleged that the drug switches resulted in increased costs to health plans and patients, primarily in follow-up doctor visits and tests. Medco claims, however, that its plans and services saved money for patients and health plans. The consent order requires Medco to pay $29 million to states for damages, fees, and restitution. Other federal allegations, however, were not settled, and that case will continue.

Two states and the District of Columbia have enacted legislation regulating PBM practices, and other states are considering such legislation.[85] Maine's statute was challenged on the basis of ERISA preemption, and the District Court issued a preliminary injunction enjoining enforcement of the law.[86]

3. Integrated Mail Order Pharmacies

As noted above, mail order has grown in importance and, for maintenance medications, can be an efficient and low-cost distribution channel. A recent study funded by the retail pharmacy industry identifies possible actions that PBMs could employ to inflate their revenues.[87] The two main actions alleged include: steering enrollees to higher priced products on which the PBM earns larger rebates, regardless of the overall cost of the drug to the health plan; and artificially inflating AWP on prescriptions filled by a PBM-owned mail order pharmacy through the use of re-labeled drugs. The authors refer to both of these practices collectively as PBM self-dealing. Though no direct evidence of self-dealing is given, the paper assumes that self-dealing could result in higher profits for PBMs and higher costs for plan sponsors.

Congress has required the Commission to study these allegations. In particular, Section 110 of the MMA requires the Commission to conduct a "Conflict of Interest Study" that includes the following:

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[84] *See* News Release, U.S. Dep't of Justice, The United States Settles Its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions (Apr. 26, 2004), *at* http://www.us doj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf.

[85] Rx Access Act of 2004, Act 15-410, 2004 Council of the Dist. of Columbia (D.C. 2004); Act to Provide for the Regulation of Pharmacy Benefits Management, H.B. 1311, 79th Leg. Assem., Reg. Sess. (S.D. 2004); Act to Protect Against Unfair Prescription Drug Practices, S.B. 194, 121st Leg., 1st Reg. Sess. (Me. 2003). See *supra* Chapter 6 for a broader discussion of the competitive implications of such mandates.

[86] Pharm. Care Mgmt. Ass'n v. Rowe, Civ. No. 03-153-B-W (D.Me. Mar. 9, 2004).

[87] JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT (2003), *available at* http://www.mpaginc.com/news/pbm report.pdf.

1. An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to mail-order pharmacies not owned by PBMs and community pharmacies.

2. Whether such group health plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

The statute requires the Commission to make any necessary recommendations concerning these allegations and to report its findings in a study by June 2005. The Commission expects that the results of this study will inform the debate about the role of PBMs in the industry.

V. DIRECT TO CONSUMER ADVERTISING

The impact of direct to consumer (DTC) advertising of prescription drugs on demand for, and the prices of, prescription drug prices has generated considerable debate. This debate has grown louder as DTC advertising has grown from $791 million in 1996 to $2.467 billion in 2000.[88] A basic tenet of competition policy is that truthful and non-misleading advertising benefits consumers.[89] The available evidence suggests that, on balance, this is true of DTC advertising of prescription drugs. Commission staff have articulated the beneficial effects of DTC advertising — as well as evidence of potential costs — in recent comments (*DTC Comments*) to the Food and Drug Administration (FDA).[90] This section briefly summarizes these comments and provides insights gained from the panelists on DTC advertising of pharmaceutical products.

A. The Effects of DTC Advertising

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[88] Magazine Publishers of America (MPA), *Comments Regarding Competition Law and Policy & Health Care (Sept.30, 2002)* 2 (Public Comment) [hereinafter MPA (public cmt)].

[89] *See, e.g.,* JOHN E. CALFEE & JANIS K. PAPPALARDO, FEDERAL TRADE COMM'N, HOW SHOULD HEALTH CLAIMS FOR FOODS BE REGULATED? AN ECONOMIC PERSPECTIVE (1989); ALISON MASSON & ROBERT L. STEINER, FEDERAL TRADE COMM'N, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS (1985).

[90] *See* Staff of the Federal Trade Commission, In the Matter of Request for Comments on Consumer-Directed Promotion, Public Hearing Dkt. No. 2003N-0344, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. 3 (Dec. 1, 2003) [hereinafter *Comments at Dec. 2003 FDA Pub. Hearing*], *available at* http://www.ftc.gov/be/ v040002text.pdf.

Commission staff have also filed other comments with the FDA on related issues. *See* Staff of the Federal Trade Commission, In the Matter of Request for Comment on First Amendment Issues, Public Hearing Dkt. No. 02N-0209, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. (Sept. 13, 2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf; Staff of the Federal Trade Commission, In the Matter of Direct-to-Consumer Promotion, Public Hearing Docket No. 95N-0227, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. (Jan. 11, 1996), *available at* www.ftc.gov/be/v960001.htm.

Panelists at the health care hearings agreed that advertising increases consumer and physician awareness of the potential benefits of pharmaceuticals and helps close the information gaps among pharmaceutical manufacturers, doctors, and consumers.[91] Panelists also presented evidence that shows some patients have been prompted by DTC advertising to talk to a doctor about a condition that they had not discussed previously.[92] One panelist stated that DTC advertising can increase compliance with pharmaceutical usage regimes and can assist in educating patients and health professionals about the risks, diagnosis, and treatment of a particular medical condition.[93]

The *DTC Comments* noted that a number of major surveys have been conducted to assess the effect of DTC advertising on consumer attitudes, experiences, and behavior. The general consensus from these and other surveys is that DTC advertising provides consumers with useful information, stimulates productive discussions between doctors and patients, and encourages consumers to learn more about previously undiagnosed conditions.[94]

Physician attitudes toward DTC advertising are mixed. An FDA survey reported that 40 percent of the physicians surveyed felt that DTC advertising had a positive effect on their patients and their practices, 30 percent felt it had a negative effect, and 30 percent felt it had no effect.[95] Another recent survey found that the most frequent complaints voiced by physicians were that DTC advertising did not provide information in a balanced manner, and that it encouraged patients to seek treatments they did not need (approximately 80 percent). On the other hand, the same survey found that more than 70 percent of physicians felt that DTC advertising helped educate patients about available treatments and 67 percent felt that it helped them have better discussions with their patients.[96]

The panelists also observed that pharmaceutical manufacturers advertise brand-name drugs to increase sales, to complement physician detailing and promotion, and to extend the

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[91] Calfee 9/10/02 at 258, 262; Raymond 9/10/02 at 279; Samp 9/10/02 at 292; Burkholder 9/10/02 at 245; *see also* MPA (public cmt), *supra* note 88, at 2-4.

[92] Calfee 9/10/02 at 262; Raymond 9/10/02 at 279.

[93] Raymond 9/10/02 at 279-81.

[94] *Comments at Dec. 2003 FDA Pub. Hearing*, *supra* note 90, at 6. This comment summarizes the major consumer surveys relating to DTC advertising of prescription drugs and is not repeated here.

[95] Kathryn Aikin, *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, Direct-To-Consumer Promotion: Public Meeting, Before the U.S. Food & Drug Admin. Ctr. for Drug Evaluation & Research (Sept. 22, 2003) (presentation slides of FDA), *available at* http://www.fda.gov/cder/ddmac/aikin/ aikin.PPT.

[96] Joel S. Weissman et al., *Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-219, 224, *at* http://content.health affairs.org/cgi/reprint/hlthaff.w4.219v1.

blockbuster nature of the drug advertised.[97] They noted that there were no DTC advertisements for generic prescription drug products, because these products rapidly gain market share by virtue of their lower prices and state laws requiring pharmacists to employ generic substitution.[98]

There remains debate regarding the impact of DTC advertising on the price and quantity sold of prescription drugs, in part due to the difficulties inherent in estimating the empirical effects. Some panelists, for example, suggested it was difficult to draw conclusions about DTC on drug utilization alone because of other forces such as increased insurance coverage of drugs, an increase in FDA approval of drugs, an increase in the diagnosis of many chronic conditions, and an increase in physician detailing and the free samples provided to physicians.[99] In their survey of the research literature, Commission staff noted that empirical evidence on the effects of DTC advertising on sales is mixed, with some studies showing a positive effect, while others do not. They described a number of more recent studies showing a pattern where DTC advertising expands the overall demand for the relevant therapeutic class of drugs, while typically failing to increase the market share of the specific drug being advertised.[100]

In regard to the price effects of DTC advertising, Commission staff noted the absence of evidence that the costs of such advertising are passed on to consumers in the form of higher prices. They also pointed out that the low volume of DTC expenditures – 2.2 percent of total prescription drug sales and 16 percent of overall drug company promotion costs – reinforces the view that such advertising would have a limited effect (if any) on price.[101] Nevertheless, staff

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[97] Findlay 9/10/02 at 269-70; Calfee 9/10/02 at 293; Samp 9/10/02 at 287-88 (noting that manufacturers advertise direct to consumers because they believe DTC advertising can increase sales); Carabello 6/12/03 at 170-71 (discussing her view that advertising is "designed to spark the interest of the health care consumer and prompt the buyer, the patient, to access or purchase services"); *see also* Lurie 9/10/02 at 272 (purpose of advertising is to get someone to buy something).

[98] Findlay 9/10/02 at 269-70; Samp 9/10/02 at 291-92.

[99] Burkholder 9/10/02 at 250; Findlay 9/10/02 at 266-68.

[100] MARTHA WOSINSKA, JUST WHAT THE PATIENT ORDERED? DIRECT-TO-CONSUMER ADVERTISING AND THE DEMAND FOR PHARMACEUTICAL PRODUCTS (Harvard Bus. School, Marketing Research Paper No. 02-04, 2002) (while DTC advertising expands total therapeutic class sales, it only increases the sales of the particular brand if the brand has a preferred status on the health insurer's formulary), *available at* http://ssrn.com/abstract_id =347005; T. IIZUKA & G. JIN, THE EFFECT OF DTC ADVERTISING IN THE PRESCRIPTION DRUG MARKETS (Univ. of Md., Working Paper, Sept. 2003); MEREDITH B. ROSENTHAL ET AL., KAISER FAMILY FOUND., DEMAND EFFECTS OF RECENT CHANGES IN PRESCRIPTION DRUG PROMOTION (2003), *available at* http://www.kff.org/ rxdrugs/loader.cfm?url=/common spot/security/getfile.cfm&PageID=14380. For a useful review of these and other empirical investigations into the demand effects of DTC advertising, see GENERAL ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS (Report to Congressional Requesters, 2002), *available at* http://www.gao.gov/new.items/ d03177.pdf.

[101] Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498 (Feb. 14, 2002). The authors also note the skewed distribution of DTC expenditures across drug classes, with the 20 largest drug classes accounting for over 60 percent of total expenditures. As a result, the relative size of DTC advertising expenditures will vary significantly across drug classes.

cautioned that the issue of price effects remains unsettled because there have been no well-controlled tests designed to directly test the claim that DTC advertising raises price. Such studies are the best test of such a hypothesis.

B. DTC Advertising of Pharmaceuticals Must Not Be False and Misleading

Panelists agreed that prescription drug promotion must be fair and balanced and include both benefit and risk information to educate and inform consumers about their health care decisions.[102] Panelists suggested that one of the contentious issues with DTC advertising of prescription drugs was whether benefits and risks were presented in an understandable manner.[103] Panelists did not claim that DTC advertisements were false and misleading.[104]

To address the concerns of conveying risks of prescription drugs in an understandable manner, the Food and Drug Administration (FDA) has sought public comment concerning whether and how it should alter its approach to regulating prescription drug advertising.[105] In late 2003, the FTC staff filed a comment with the FDA suggesting that consumers and competition would benefit if the FDA adopted more consumer-friendly and less burdensome risk disclosure requirements.[106] In early 2004, the FDA issued and sought public comment on three draft guidance documents designed to improve communications to consumers and health care practitioners about health conditions and medical products.[107] In May 2004, FTC staff filed a comment generally supporting the changes reflected in these guidance documents, but also recommending that the FDA conduct consumer research concerning the risk disclosures they would require.[108] The FDA continues to work with industry and other interested parties to determine the best way to inform consumers on prescription drug issues.

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[102] *See generally*, panel discussion 9/10/02 at 245-300. For an overview of the Food and Drug Administration's regulation of DTC advertisements, see Frank 9/10/02 at 231-42.

[103] Samp 9/10/02 at 290; *see also* Burkholder 9/10/02 at 252.

[104] Findlay 9/10/02 at 297.

[105] For an economic analysis of the costs and benefits of drug advertising restrictions, including the effect of FDA's regulations on these costs and benefits, see J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 SETON HALL L.J. 1370 (1994).

[106] *See Comments at Dec. 2003 FDA Pub. Hearing*, *supra* note 90, at 3.

[107] *See* News Release, Food & Drug Admin., New FDA Draft Guidance Aim to Improve Health Information (Feb. 4, 2004), *at* http://www.fda.gov/bbs/topics/NEWS/2004/NEW01016.html.

[108] *See* Staff of the Federal Trade Commission, In the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion, Public Hearing Dkt. No. 2004D-0042, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. (May 10, 2004), *available at* http://www.ftc.gov/os/2004/05/040512dtcdrugscomment.pdf.